

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



MLN Matters® Number: MM9115 **Revised** Related Change Request (CR) #: CR 9115
Related CR Release Date: December 30, 2015 Effective Date: October 9, 2014
Related CR Transmittal #: R188NCD and R3319CP Implementation Date: September 8, 2015 for non-shared MAC edits; January 4, 2016 for shared systems changes

National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test

Note: This article was revised on January 5, 2016, to reflect the revised CR9115 issued on December 30, 2015. The CR was revised to show that HCPCS code G0464 expired on December 31, 2015, and is replaced in the 2016 Clinical Laboratory Fee Schedule with CPT code 81528. The article is revised to reflect this change. Also, the CR release date, transmittal number, and the Web address for accessing the CR are changed. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for colorectal screening tests provided to Medicare beneficiaries.

Provider Action Needed



STOP – Impact to You

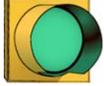
This article is based on Change Request (CR) 9115 which announces effective October 9, 2014, the Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover Cologuard™ - a multitarget stool DNA test – as a colorectal cancer screening test for asymptomatic, average risk beneficiaries, aged 50 to 85 years.

Disclaimer

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**CAUTION – What You Need to Know**

CR9115 instructs the MACs that effective for claims with dates of service on or after October 9, 2014, Medicare will recognize new Healthcare Common Procedure Coding System (HCPCS) code G0464, (Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (for example, KRAS, NDRG4 and BMP3)) as a covered service. Only laboratories authorized by the manufacturer to perform the Cologuard™ test may bill for this service.

**GO – What You Need to Do**

Make sure that your billing staff are aware of these changes.

Background

The Social Security Act (the Act) (Sections 1861(s)(2)(R) and 1861(pp) - see http://www.ssa.gov/OP_Home/ssact/title18/1861.htm) and regulations at 42 CFR 410.37 (see <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec410-37.pdf>) authorize coverage for screening colorectal cancer (CRC) tests under Medicare Part B. The statute and regulations authorize the Secretary to add other tests and procedures (and modifications to such tests and procedures for colorectal cancer screening) as the Secretary determines appropriate in consultation with appropriate experts and organizations.

As part of the CMS – Food and Drug Administration (FDA) Parallel Review Pilot Program, CMS finalized a NCD for Screening for CRC Using Cologuard™ - A Multitarget Stool DNA Test. After considering public comments and consulting with appropriate organizations, effective October 9, 2014, CMS has determined that the evidence is sufficient to cover Cologuard™ - a multitarget stool DNA test – as a colorectal cancer screening test for asymptomatic, average risk beneficiaries, who are ages 50 to 85 years.

Effective for claims with dates of service on or after October 9, 2014, MACs will recognize the new HCPCS code G0464 as a covered service. Be aware that claims for HCPCS code G0464 must also include ICD-9 diagnosis codes V76.41 and V76.51. Once ICD-10 is implemented, the claim must reflect ICD-10 diagnosis codes Z12.12 and Z12.11.

MACs will only pay for HCPCS code G0464 when it is submitted on Types of Bill (TOB) 13X (hospital outpatient departments), 14X (hospital non-patient laboratories), or 85X (critical access hospitals). Payments will be made on TOB 13X and 14X based on the clinical laboratory fee schedule (CLFS). Payment for TOB 85X will be based on reasonable cost.

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Note: HCPCS code G0464 is in the January 1, 2015 CLFS and Integrated Outpatient Code Editor (IOCE) updates with an effective date of October 9, 2014. Therefore, MACs shall apply contractor pricing to claims containing HCPCS G0464 with dates of service October 9, 2014, through December 31, 2014. However, in the 2016 CLFS, G0464 expires effective December 31, 2015, and effective January 1, 2016, CPT code 81528 replaces G0464.

You can refer to the revised Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 210.3, Colorectal Cancer Screening Tests, for coverage policy. For claims processing instructions, refer to revised Pub. 100-04, Medicare Claims Processing Manual, Chapter 18, Section 60, Colorectal Cancer Screening. Both of these revised manuals are included as attachments to CR9115.

Effective for dates of service on or after October 9, 2014, Medicare Part B will cover the Cologuard™ test once every 3 years for Medicare beneficiaries that meet all of the following criteria:

- Age 50 to 85 years;
- Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test); and
- At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

There is no coinsurance or deductible for tests paid under the CLFS. Therefore, there is no coinsurance or deductible for HCPCS code G0464.

Medicare will pay for this service for eligible beneficiaries only once every 3 years. Next eligible dates will be displayed on all Common Working File (CWF) provider query screens. Subsequent claim lines for HCPCS code G0464 received in the same 3-year period will be denied using the following:

- Claim Adjustment Reason Code (CARC) 119 - "Benefit maximum for this time period has been reached;"
- Remittance Advice Remarks Code (RARC) N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD;" and
- Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed Advance Beneficiary Notice (ABN) is on file.

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To be eligible for this service, beneficiaries must be aged 50-85 or the claim line item will be denied with the following messages:

- CARC 6 - “The procedure/revenue code is inconsistent with the patient's age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N129 - “Not eligible due to the patient’s age.”
- Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

Failure to include the required ICD-9 or ICD-10 codes on the claim line will result in denial of the claim line with the following messages:

- CARC 167 – “This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N386 - “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp on the CMS website. If you do not have web access, you may contact the contractor to request a copy of the NCD.”
- Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

Claim line items submitted on TOBs other than 13X, 14X, or 85X will be denied with the following messages:

- CARC 170: “Payment is denied when performed/billed by this type of provider. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N95 – “This provider type/provider specialty may not bill this service.”
- Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

All other indications for colorectal cancer screening not otherwise specified in the Act and regulations, or otherwise specified in Section 210.3 of the NCD Manual, remain nationally non-covered.

Additional Information

The official instruction, CR9115, was issued to your MAC regarding this change via two transmittals. The first updates the “Medicare National Coverage Determinations Manual” and it is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R188NCD.pdf> on the CMS website. The

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second transmittal updates the “Medicare Claims Processing Manual” and it is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3319CP.pdf> on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under “How Does It Work.”

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